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| Attorney's Docket No. 17248-004US1/ 4804US | Hand Delivered by Mooreland and Moore on July 21, 2005 | Mailing Date July 20, 2005 | For PTO Use Only <i>Do Not Mark in This Area</i> |
| Application No. 10/516,785 | Filing Date December 3, 2004 | Attorney/Secretary Init SZS/kGP/kzf | |
| Title of the Application LIGHT EMITTING MICROORGANISMS AND CELLS FOR DIAGNOSIS AND THERAPY OF DISEASES ASSOCIATED WITH WOUNDED OR INFLAMED TISSUE | | | |
| Applicant Aladar A. Szalay et al. | | | |
| Enclosures ·Transmittal Letter (1 page in duplicate) ·Information Disclosure Statement (2 pages) ·Form PTO-1449 (19 pages) ·Documents listed on the Form PTO-1449 (6 volumes in 2 boxes); And this Return Postcard | | | |

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July 20, 2005

Mooreland & Moore
2001 Jefferson Davis Hwy.
Suite 302
Arlington, VA 22202

Re: Light emitting microorganisms and cells for diagnosis and therapy of
diseases associated with wounded or inflamed tissue

Our Ref.: 17248-004US1 / 4804US

Dear Gentlemen:

Please deliver the enclosed documents to the U.S. Patent and Trademark Office Mail Room on Thursday, July 21, 2005. The documents enclosed are a Transmittal letter, Information Disclosure Statement, Form PTO-1449 (19 pages), Cited References (2 boxes containing 6 volumes), and a return postcard. In addition, please have the enclosed postcard date-stamped by the PTO and returned to us at your earliest convenience. We would also appreciate receiving a confirmation from you indicating that delivery of the enclosed documents has been made.

Thank you for your assistance in this matter. If you have any questions, please do not hesitate to contact our office.

Sincerely,

Stephanie L. Seidman

SZS/KGP/kzf

Enclosure

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Aladar A. Szalay et al. Art Unit : 1645
Serial No. : 10/516,785 Examiner : Unknown
Filed : December 03, 2004 Confirm. No.: 7336
Customer No.: 20985
Title : Light emitting microorganisms and cells for diagnosis and therapy of diseases
 associated with wounded or inflamed tissue

Mail Stop: Amendment

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Transmitted herewith are an Information Disclosure Statement, Forms PTO-1449 (19 pages), and copies of cited non US patent references for filing in connection with the above-identified application. Because this Information Disclosure Statement is filed prior to receipt of a first office action on the merits in the above-referenced application, no fee is due. However, should it be determined that a fee for filing these papers is required, the Commissioner is authorized to charge Deposit Account No. 06-1050, as stated below:

☒ The Commissioner is hereby authorized to charge any fees that may be due in connection with this paper or with this application during its entire pendency to Deposit Account No. 06-1050. A duplicate of this sheet is enclosed.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

Dated: July 20, 2005
Attorney Docket No. 17248-004US1 / 4804US
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Applicant : Aladar A. Szalay et al.
Serial No. : 10/516,785
Filed : December 03, 2004
Information Disclosure Statement
Page : 2 of 2

Attorney's Docket No.: 17248-004US1 / 4804US

Applicant also makes known to the Examiner the following pending U.S., European and International applications that have one or more common inventors and/or are commonly owned:

| <u>U.S.S.N. (App. No.)</u> | <u>Filing Date</u> | <u>Matter No.</u> |
|----------------------------|--------------------|-------------------|
| US 10/872,156 | 06/18/04 | 002001 (4802) |
| US 10/866,606 | 06/10/04 | 003002 (4803B) |
| US 10/485,179 | 11/05/04 | 003US1 (4803US) |
| US 10/849,664 | 05/19/04 | 004002 (4804B) |

| <u>Int'l App. No.</u> | <u>Filing Date</u> | <u>Matter No.</u> |
|-----------------------|--------------------|-------------------|
| PCT/US04/19866 | 06/18/04 | 002WO1 (4802PC) |
| EP 020794632.6 | 01/28/04 | 003EP3 (4803CEP) |
| EP 02012552.2 | 06/05/02 | 004EP1 (4804EP) |
| EP 03735553.4 | 06/05/03 | 004EP2 (4804BEP) |
| EP 03018478.2 | 08/14/03 | 005EP1 (4805EP) |
| EP 03024283.8 | 10/22/03 | 006EP1 (4806EP) |

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and they be made of record in the file history of the above-captioned application.

Respectfully submitted,

Stephanie L. Seidman
Reg. No. 33,779

Dated: July 20, 2005
Attorney Docket No. 17248-004US1 / 4804US
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| Substitute Form PTO-1449 (Modified) | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 17248-004US1/ 4804US | Application No. 10/516,785 |
| List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | | Applicant Szalay et al. | |
| | | Filing Date December 3, 2004 | Group Art Unit 1645 |

U.S. Patent Documents

| Examiner Initial | Desig. ID | Document Number | Publication Date | Patentee | Class | Subclass | Filing Date If Appropriate |
|------------------|-----------|-----------------|------------------|--------------------|-------|----------|----------------------------|
| | A | 2003/0228261 | 12/11/03 | Szalay et al. | 424 | 9.34 | 06/05/02 |
| | B | 2003/0213007 | 11/13/03 | Slattery et al. | 800 | 15 | 03/26/03 |
| | C | 2002/0160970 | 10/31/02 | Hadlaczky et al. | 514 | 44 | 03/05/01 |
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| | F | 2003/0133949 | 07/17/03 | Szalay et al. | 424 | 200.1 | 01/30/03 |
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| | Applicant Szalay et al. | | |
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Foreign Patent Documents or Published Foreign Patent Applications

| Examiner Initial | Desig. ID | Document Number | Publication Date | Country or Patent Office | Class | Subclass | Translation | |
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| | | | | | | | Yes | No |
| | AW | 00/47237 | 08/17/00 | PCT | | | | |
| | AX | 01/05229 | 1/25/01 | PCT | | | | |
| | AY | 01/14579 | 03/01/01 | PCT | | | | |

Examiner Signature

Date Considered

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| | Applicant Szalay et al. | | |
| | Filing Date December 3, 2004 | Group Art Unit 1645 | |

Foreign Patent Documents or Published Foreign Patent Applications

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| | | | | | | | Yes | No |
| | AZ | 01/18195 | 03/15/01 | PCT | | | | |
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| | BE | 1 281 767 | 05/28/03 | EP | | | | |
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| | BH | 91/07989 | 06/13/91 | PCT | | | | |
| | BI | 94/10302 | 05/11/94 | PCT | | | | X* |

X*= An English Language Derwent abstract is being provided

Other Documents (include Author, Title, Date, and Place of Publication)

| Examiner Initial | Desig. ID | Document |
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| | BJ | Advisory Committee on Immunization Practices (ACIP), "Smallpox vaccination and adverse reactions: guidance for clinicians", Morbidity and Mortality Weekly Report 52(RR-4): 1-29 (February 21, 2003) |
| | BK | Advisory Committee on Immunization Practices (ACIP), "Vaccinia (smallpox) vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR, 50(RR-10): 1-26 & ce1-ce7 (June 22, 2001) |
| | BL | Aebischer et al., "Long-Term Cross-Species Brain Transplantation of a Polymer-Encapsulated Dopamine-Secreting Cell Line," Experimental Neurology 111:269-275 (1991) |
| | BM | Aebischer et al., "Functional Recovery in Hemiparkinsonian Primates Transplanted with Polymer-Encapsulated PC12 Cells," Experimental Neurology 126:151-158 (1994) |
| | BN | Aguilar, O.M. et al., "The <i>nifEN</i> genes participating in FeMo cofactor biosynthesis and genes encoding dinitrogenase are part of the same operon in <i>Bradyrhizobium</i> species. Mol Gen Genet. 224(3):413-20 (1990) |
| | BO | Alcami, A. et al., "Vaccinia virus strains Lister, USSR and Evans express soluble and cell-surface tumour necrosis factor receptors," J. Gen. Virol., 80: 949-959 (1999) |
| | BP | Antoine, G. et al., "Characterization of the vaccinia MVA hemagglutinin gene locus and its evaluation as an insertion site for foreign genes," Gene, 177: 43-46 (1996) |
| | BQ | Arakawa, S. et al., "Clinical trial of attenuated vaccinia virus AS strain in the treatment of advanced adenocarcinoma," J. Cancer Res. Clin. Oncol., 113: 95-98 (1987) |
| | BR | Baeksgaard, L. and J.B. Sorensen, "Acute tumor lysis syndrome in solid tumors--a case report and review of the literature," Cancer Chemother. Pharmacol., 51: 187-192 (2003). |
| | BS | Baker, R.O. et al., "Potential antiviral therapeutics for smallpox, monkeypox, and other orthopoxvirus infections," Antiviral Research, 57: 13-23 (2003) |

Examiner Signature

Date Considered

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| | | Filing Date December 3, 2004 | Group Art Unit 1645 |

Other Documents (include Author, Title, Date, and Place of Publication)

| Examiner Initial | Desig. ID | Document |
|------------------|-----------|---|
| | BT | Balkwill, F., "Chemokine biology in cancer," <i>Seminars in Immunol.</i> , 15: 49-55 (2003) |
| | BU | Baxby, D., "Poxviruses," Chapter 15 in <i>Principles and Practice of Clinical Virology</i> , Zuckerman, A.J. et al.(eds.), John Wiley & Sons Ltd., pp. 451-465 (2000) |
| | BV | Beebe, J.L. and E.W. Koneman, "Recovery of Uncommon Bacteria from Blood: Association with Neoplastic Disease," <i>Clin. Microbiol. Rev.</i> , 8(3): 336-356 (1995) |
| | BW | Beerntsen, B.T. et al., "Genetics of Mosquito Vector Competenc," <i>Microbiol. Mol. Biol. Rev.</i> , 64(1): 115-137 (2000) |
| | BX | Belas et al., "Bacterial Bioluminescence: Isolation and Expression of the Luciferase Genes from <i>Vibrio harveyi</i> ," <i>Science</i> , 218: 791-793 (1982) |
| | BY | Bell, J.C. et al., "Getting oncolytic virus therapies off the ground," <i>Cancer Cell</i> , 4: 7-11 (2003) |
| | BZ | Bendig, M.M., "The production of foreign proteins in mammalian cells," <i>Genetic Engineering</i> 7:91-127 (1988) |
| | CA | Bergsland, E.K. and A.P. Venook, "Shedding Old Paradigms: Developing Viruses to Treat Cancer," <i>J. Clin. Oncol.</i> , 20(9): 2220-2222 (2002) |
| | CB | Bermudes et al., "Live bacteria as anticancer agents and tumor-selective protein delivery vectors," <i>Current Opinion in Drug Discovery & Development</i> 5(2):194-199 (2002) |
| | CC | Best et al., "Baboon/human homologies examined by spectral karyotyping (SKY): a visual comparison," <i>Cytogenet Cell Genet.</i> 82(1-2):83-7 (1998) |
| | CD | Bickels, J. et al., "Coley's toxin: historical perspective," <i>Isr. Med. Assoc. J.</i> , 4(6): 471-472 (2002) |
| | CE | Blanchard, T.J. et al., "Modified vaccinia virus Ankara undergoes limited replication in human cells and lacks several immunomodulatory proteins: implications for use as a human vaccine," <i>Journal of General Virology</i> , 79: 1159-1167 (1998) |
| | CF | Blasco, R. and B. Moss, "Selection of recombinant vaccinia viruses on the basis of plaque formation," <i>Gene</i> , 158: 157-162 (1995) |
| | CG | Bogdahn et al., "Autocrine Tumor Cell Growth-inhibiting Activities from Human Malignant Melanoma," <i>Cancer Research</i> 49:5358-5363 (1989) |
| | CH | Borellini, F. and J.M. Ostrove, "The Transfer of Technology from the Laboratory to the Clinic: In Process Controls and Final Product Testing," Chapter 18 in <i>Gene Therapy Technologies, Applications and Regulations</i> , A. Meager (Ed.), John Wiley & Sons Ltd., pp. 359-373 (1999) |
| | CI | Boulanger, D. et al., "Morphogenesis and release of fowlpox virusm," <i>Journal of General Virology</i> , 81: 675-687 (2000) |
| | CJ | Bouvier et al., "Functional characterization of the human dopamine D-4.2 receptor using vaccinia virus as an expression system," <i>European Journal of Pharmacology</i> 290(1):11-17 (1995) |
| | CK | Boyd, J.E., "Facilities for Large-Scale Production of Vectors under GMP Conditions," Chapter 20 in <i>Gene Therapy Technologies, Applications and Regulations</i> , A. Meager (Ed.), pp. 383-400 (1999) |
| | CL | Brain, J.D. et al., "Pulmonary intravascular macrophages: their contribution to the mononuclear phagocyte system in 13 species", <i>Am. J. Physiol.</i> , 276(1 pt 1): L146-L154 (1999) |
| | CM | Breman, J.G. and D.A. Henderson, "Diagnosis and Management of Smallpox," <i>N. Engl. J. Med.</i> , 346(17): 1300-1308 (2002) |
| | CN | Broder, C.C. et al., "Expression of foreign genes in cultured human primary macrophages using recombinant vaccinia virus vectors," <i>Gene</i> , 142: 167-174 (1994) |

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| Other Documents (include Author, Title, Date, and Place of Publication) | | | | | |
| Examiner Initial | Desig. ID | Document | | | |
| | CO | Broyles, S.S., "Vaccinia virus transcription," Journal of General Virology, 84: 2293-2303 (2003) | | | |
| | CP | Brunke M et al., "Luciferase assembly after transport into mammalian microsomes involves molecular chaperones and peptidyl-prolyl cis/trans-isomerases," J Biol Chem. 271(38):23487-94 (1996) | | | |
| | CQ | Carroll, S.F. and R.J. Collier, "Active Site of Pseudomonas aeruginosa Exotoxin A," J. Biol. Chem. 262:8707-8711 (1987) | | | |
| | CR | Carter, G.C. et al., "Vaccinia virus cores are transported on microtubules," Journal of General Virology, 84: 2443-2458 (2003) | | | |
| | CS | Cavanagh, L.L. and U.H. von Andrian, "Travellers in many guises: The origins and destinations of dendritic cells," Immunology and Cell Biology, 80: 448-462 (2002) | | | |
| | CT | Chalfie et al., "Green Fluorescent Protein as a Marker for Gene Expression," Science 263: 802-805 (1994) | | | |
| | CU | Chambers, A.F. et al., "Dissemination and Growth of Cancer Cells in Metastatic Sites," Nat. Rev. Cancer, 2: 563-572 (2002) | | | |
| | CV | Chambers, A.F. et al., "Molecular biology of breast cancer metastasis Clinical implications of experimental studies on metastatic inefficiency," Breast Cancer Res., 2: 400-407 (2000) | | | |
| | CW | Chaudhary et al., "Role of domain II of Pseudomonas exotoxin in the secretion of proteins into the periplasm and medium by Escherichia coli," Proc. Natl. Acad. Sci. USA 85: 2939-2943 (1988) | | | |
| | CX | Cheadle, E.J. and A.M. Jackson, "Bugs as Drugs for Cancer," Immunology 107: 10-19 (2002) | | | |
| | DA | Chen et al. "Evaluation of combined vaccinia virus-mediated antitumor gene therapy with p53, IL-2, and IL-12 in a glioma model." Cancer Gene Ther. 7(11):1437-47 (2000) | | | |
| | DB | Chen et al. "Cancer gene therapy by direct tumor injections of a nonviral T7 vector encoding a thymidine kinase gene," Hum Gene Ther. 9(5):729-36 (1998) | | | |
| | DC | Chiocca, E.A., "Oncolytic Viruses," Nat. Rev. Cancer, 2(12): 938-950 (2002) | | | |
| | DD | Choi et al., "Efficient secretory production of alkaline phosphatase by high cell density culture of recombinant Escherichia coli using the Bacillus sp. endoxylanase signal sequence," Appl. Microbiol. Biotechnol. 53:640-645 (2000) | | | |
| | DE | Cichutek, K., "Development and Regulation of Gene Therapy Drugs in Germany," Chapter 17 in Gene Therapy Technologies, Applications and Regulations, A. Meager (Ed.), John Wiley & Sons Ltd. pp. 347-358 (c1999) | | | |
| | DF | Clairmont, C. et al., "Enhanced antitumor activity from tumor-targeting Salmonella expressing endostatin," American Association for Cancer Research: 91st Annual Meeting of the AACR, April 1-5, 2000, 41:732 Abstract #4653 (2000) | | | |
| | DG | Compton, J.L. and A.A. Szalay, "Insertion of nonhomologous DNA into the yeast genome mediated by homologous recombination with a cotransforming plasmid," Mol Gen Genet. 188(1):44-50 (1982) | | | |
| | DH | Condeelis, J. and J.E. Segall, "Intravital imaging of cell movement in tumours," Nat. Rev. Cancer, 3: 921-930 (2003) | | | |
| | DI | Contag et al., "Photonic detection of bacterial pathogens in living hosts," Mol. Microbiol. 18: 593-603 (1995) | | | |

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| | | | Filing Date December 3, 2004 | Group Art Unit 1645 |
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| | DJ | Coupar, B.E.H. et al., "A general method for the construction of recombinant vaccinia viruses expressing multiple foreign genes," Gene, 68: 1-10 (1988) | | |
| | DK | Coussens, L.M. and Z. Werb, "Inflammation and cancer," Nature, 420: 860-867 (2002) | | |
| | DL | Craperi et al. "Increased bax expression is associated with cell death induced by ganciclovir in a herpes thymidine kinase gene-expressing glioma cell line." Hum Gene Ther. 10(4):679-688 (1999) | | |
| | DM | Cseh, S. et al., "Rapid freezing of mouse embryos in ethylene glycol at different preimplantation stages," Acta Veterinaria Hungarica 44(4):457-65 (1996) | | |
| | DN | Culver et al., "In vivo gene transfer with retroviral vector-producer cells for treatment of experimental brain tumors." Science. 256(5063):1550-2 (1992) | | |
| | DO | Davis, C. et al., "The role of inflammation in vascular injury and repair," Journal of Thrombosis and Haemostasis, 1: 1699-1709 (2003) | | |
| | DP | De Clercq, E., "Cidofovir in the therapy and short-term prophylaxis of poxvirus infections," Trends in Pharmacological Sciences, 23(10): 456-458 (2002) | | |
| | DQ | Demers, G.W. et al., "Pharmacologic Indicators of Antitumor Efficacy for Oncolytic Virotherapy", Cancer Res., 63: 4003-4008 (2003) | | |
| | DR | Derwent English abstract for WO 94/10302, published May 11, 1994 entitled: "Vectors inhibiting HIV replication in potential host cells - contg. DNA encoding Pol, Gag, Env, Rev, and/or Tat in antisense direction and further DNA causing spontaneous amplification," Accession Nbr. 1994-152544 [19] | | |
| | DS | de Wet et al., "Firefly Luciferase Gene: Structure and Expression in Mammalian Cells," Mol. Cell. Biol. 7: 725-737 (1987) | | |
| | DT | Diamond, D.C. ET AL. "Sequence comparison of baboon ABO histo-blood group alleles: lesions found in O alleles differ between human and baboon," Blood Cells Mol Dis. 23(2):242-51 (1997) | | |
| | DU | Diamond, D.C., et al., "Genotyping the baboon ABO histo-blood group locus by two-color fluorescence SSCP," Biotechniques 27(5):1054, 1056, 1058-59, 1061 (1999) | | |
| | DV | Dietrich, G. et al., "Delivery of antigen-encoding plasmid DNA into the cytosol of macrophages by attenuated suicide <i>Listeria monocytogenes</i> ," Nat Biotechnol. 16(2):181-5 (1998) | | |
| | DW | Ding et al., "Zinc-dependent dimers observed in crystals of human endostatin," Proc. Natl. Acad. Sci. USA 95:10443-10448 (1998) | | |
| | DX | Dobbelstein, M., "Viruses in therapy-- royal road or dead end?", Virus Research, 92: 219-221 (2003) | | |
| | DY | Domí, A. and B. Moss, "Cloning the vaccinia virus genome as a bacterial artificial chromosome in <i>Escherichia coli</i> and recovery of infectious virus in mammalian cells," Proc. Natl. Acad. Sci. U.S.A., 99(19): 12415-12420 (2002) | | |
| | DZ | Dull et al., "Insulin-like growth factor II precursor gene organization in relation to insulin gene therapy," Nature 310: 777-781 (1984) | | |
| | EA | Eastham et al. "Prostate cancer gene therapy: herpes simplex virus thymidine kinase gene transduction followed by ganciclovir in mouse and human prostate cancer models." Hum Gene Ther. 7(4):515-23 (1996) | | |
| | EB | Ehrensgruber, M.U., "Alphaviral gene transfer in neurobiology," Brain Research Bulletin, 59(1): 13-22 (2002) | | |
| | EC | Engbrecht et al., "Measuring Gene Expression with Light," Science 227: 1345-1347 (1985) | | |

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| | EA | Escher, A. et al., "Bacterial luciferase $\alpha\beta$ fusion protein is fully active as a monomer and highly sensitive <i>in vivo</i> to elevated temperature," Proc Natl Acad Sci U S A. 86(17):6528-32 (1989) | | |
| | EB | Escher, A et al., "The β subunit polypeptide of <i>Vibrio harveyi</i> luciferase determines light emission at 42° C," Mol Gen Genet. 230(3):385-93 (1991) | | |
| | EC | Escher, A. and A.A. Szalay, "GroE-mediated folding of bacterial luciferases <i>in vivo</i> ," Mol Gen Genet. 238(1-2):65-73 (1993) | | |
| | ED | Esposito, J.J. and F. Fenner, "Poxviruses", Chapter 85 in Field's Virology, 4th Edn., vol. 2, pp. 2885-2921. Edited by D. M. Knipe and P. M. Howley, Philadelphia: Lippincott Williams & Wilkins, (2001) | | |
| | EE | Fatyol, K et al., "Mer22-related sequence elements form pericentric repetitive DNA families in primates," Mol Gen Genet. 262(6):931-9 (2000) | | |
| | EF | Fatyol, K et al. "Molecular characterization of a stably transformed <i>Bombyx mori</i> cell line: identification of alternative transcriptional initiation sites of the A3 cytoplasmic actin gene." Mol Gen Genet. 260(1):1-8 (1998) | | |
| | EG | Fatyol, K et al., "An alternative intronic promoter of the Bombyx A3 cytoplasmic actin gene exhibits a high level of transcriptional activity in mammalian cells," Mol Gen Genet. 261(2):337-45 (1999) | | |
| | EH | Fatyol, K and A.A. Szalay, "The p14 ^{ARF} tumor suppressor protein facilitates nucleolar sequestration of hypoxia-inducible factor-1 α (HIF-1 α) and inhibits HIF-1-mediated transcription," J Biol Chem. 276(30):28421-28429 (2001) | | |
| | EI | Fernández-Piñas, F. and C.P. Wolk, "Expression of <i>luxCD-E</i> in <i>Anabaena</i> sp. can replace the use of exogenous aldehyde for <i>in vivo</i> localization of transcription by <i>luxAB</i> ," Gene 150:169-174 (1994) | | |
| | EJ | Fidler, I.J., "The pathogenesis of cancer metastasis: the 'seed and soil' hypothesis revisited," Nature Cancer Research, 3: 1-6 (2003) | | |
| | EK | Foran, D.R. and W.M. Brown, "Nucleotide sequence of the LuxA and LuxB genes of the bioluminescent marine bacterium <i>Vibrio fischeri</i> ," Nucleic Acids Res. 16: 777 (1988) | | |
| | EL | Forbes, N.S. et al., "Sparse Initial Entrapment of Systematically Injected <i>Salmonella typhimurium</i> Leads to Heterogenous Accumulation within Tumors," Cancer Res., 63: 5188-5193 (2003) | | |
| | EM | Fox, A.W., "Emergency and Compassionate-use INDs and Accelerated NDS or ANDA Approvals--Procedures, Benefits and Pitfalls," Chapter 26 in Principles and Practice of Pharmaceutical Medicine, A.J. Fletcher, et al.(Eds.), John Wiley & Sons, pp.299-305, (2002) | | |
| | EN | Freed et al., "Survival of Implanted Fetal Dopamine Cells and Neurologic Improvement 12 to 46 Months After Transplantation for Parkinson's Disease," New England Journal of Medicine 327:1549-1555 (1992) | | |
| | EO | Freitag, N.E. and K.E. Jacobs, "Examination of <i>Listeria monocytogenes</i> Intracellular Gene Expression by Using Green Fluorescent Protein of <i>Aequorea victoria</i> ," Infect.Immun. 67:1844-1852 (1999) | | |
| | EP | Friberg, S. and S. Mattson, "On the Growth Rates of Human Malignant Tumors: Implications for Medical Decision Making," Journal of Surgical Oncology, 65: 284-297 (1997) | | |
| | EQ | Gallagher, R., "Vaccination Undermined," The Scientist, 17(22): 1-3 (2003) | | |
| | ER | Geng, J.G., "Directional migration of leukocytes: their pathological roles in inflammation and strategies for development of anti-inflammatory therapies," Cell Res., 11(2): 85-88 (2001) | | |

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| | ES | Geng, J.G., "Interaction of vascular endothelial cells with leukocytes, platelets and cancer cells in inflammation, thrombosis and cancer growth and metastasis," Acta Pharmacol. Sin, 24(12): 1297-1300 (2003) | | | | | |
| | ET | Giacomin, L.T. and A.A. Szalay, "Expression of a PALI promoter luciferase gene function in <i>Arabidopsis thaliana</i> in response to infection by phytopathogenic bacteria," Plant Sci. 116: 59-72 (1996) | | | | | |
| | EU | Gnant, M.F.X. et al, "Tumor-Specific Gene Delivery Using Recombinant Vaccinia Virus in a Rabbit Model of Liver Metastases", Journal of the National Cancer Institute, 91(20): 1744-1750 (1999) | | | | | |
| | EV | Goetz et al., "Multicenter Study of Autologous Adrenal Medullary Transplantation to the Corpus Striatum in Patients with Advanced Parkinson's Disease", N. Eng. J. Med. 320:337-341 (1989) | | | | | |
| | EW | Goetz, M et al., "Microinjection and growth of bacteria in the cytosol of mammalian host cells," Proc Natl Acad Sci U S A. 98(21):12221-12226. (2001) | | | | | |
| | EX | Gomella, L.G. et al., "Phase I Study Of Intravesical Vaccinia Virus As A Vector For Gene Therapy Of Bladder Cancer", J. Urology, 166: 1291-1295 (2001) | | | | | |
| | EY | Gómez, C.E. and M. Esteban, "Recombinant proteins produced by vaccinia virus vectors can be incorporated within the virion (IMV form) into different compartments," Arch. Virol., 146: 875-892 (2001) | | | | | |
| | EZ | Graff, C.P. and K.D. Wittrup, "Theoretical Analysis of Antibody Targeting of Tumor Spheroids: Importance of Dosage for Penetration, and Affinity for Retention," Cancer Res., 63: 1288-1296 (2003) | | | | | |
| | FA | Gray, J.W., "Evidence emerges for early metastasis and parallel evolution of primary and metastatic tumors", Cancer Cell, 4(1): 4-6 (2003) | | | | | |
| | FB | Green, D.R. and G.I. Evan, "A matter of life and death", Cancer Cell, 1: 19-30 (2002) | | | | | |
| | FC | Greer III, L.F. and A.A. Szalay, "Imaging of light emission from the expression of luciferases in living cells and organisms: a review," Luminescence. 17(1):43-74 (2002) | | | | | |
| | FD | Griffin, D.E., "A Review of Alphavirus Replication in Neurons," Neuroscience and Biobehavioral Reviews, 22(6): 721-723 (1998) | | | | | |
| | FE | Grove et al. "Virus-directed enzyme prodrug therapy using CB1954" Anti-Cancer Drug Design 14(6) 461-472 (1999) | | | | | |
| | FF | Guy et al., "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease," Proc. Natl. Acad. Sci. USA 89: 10578-10582 (1992) | | | | | |
| | FG | Hacein-Bey-Abina, S. et al., "A Serious Adverse Event after Successful Gene Therapy for X-Linked Severe Combined Immunodeficiency", N. Engl. J. Med., 348(3): 255-266 (2003) | | | | | |
| | FH | Hadley, R.G. et al., "Conservation of DNA regions adjacent to <i>nifKDH</i> homologous sequences in diverse slow-growing <i>Rhizobium</i> strains," J Mol Appl Genet. 2(3):225-36 (1983) | | | | | |
| | FI | Haghighat et al. "Antitumor effect of IL-2, p53, and bax gene transfer in C6 glioma cells," Anticancer Res. 20(3A):1337-42 (2000) | | | | | |
| | FJ | Hall et al., "Adenovirus-mediated herpes simplex virus thymidine kinase gene and ganciclovir therapy leads to systemic activity against spontaneous and induced metastasis in an orthotopic mouse model of prostate cancer," Int J Cancer. 70(2):183-7 (1997) | | | | | |
| | FK | Halsell, J.S. et al., "Myopericarditis Following Smallpox Vaccination Among Vaccinia-Naïve US Military Personnel", J. Am. Med. Assoc., 289(24): 3283-3289 (2003) | | | | | |

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| | FL | Hanahan, D. and R.A. Weinberg, "The Hallmarks of Cancer", Cell, 100: 57-70 (2000) |
| | FM | Hansen, R.M. and J.A. Libnoch, "Remission of Chronic Lymphocytic Leukemia After Smallpox Vaccination," Arch. Intern. Med., 138: 1137-1138 (1978) |
| | FN | Hawkins, L.K. et al., "Oncolytic biotherapy: a novel therapeutic platform," The Lancet Oncology, 3: 17-26 (2002) |
| | FO | Hemann et al., "High-Copy Expression Vector Based on Amplification-Promoting Sequences", DNA and Cell Biology 13:437-445 (1994) |
| | FP | Hermiston, T.W. and I. Kuhn, "Armed therapeutic viruses: Strategies and challenges to arming oncolytic viruses with therapeutic genes," Cancer Gene Therapy, 9: 1022-1035 (2002) |
| | FQ | Hershey, P. et al., "Adjuvant Immunotherapy of Patients With High-Risk Melanoma Using Vaccinia Viral Lysates of Melanoma: Results of a Randomized Trial," Journal of Clinical Oncology, 20(20): 4181-4190 (2002) |
| | FR | Hess et al., " <i>Listeria monocytogenes</i> p60 supports host cell invasion by and in vivo survival of attenuated <i>Salmonella typhimurium</i> ," Infect Immun. 63(5):2047-53 (1995) |
| | FS | Hollinshead, M. et al., "Vaccinia virus utilizes microtubules for movement to the cell surface," Journal of Cell Biology, 154: 389-402 (2001) |
| | FT | Holló, G et al., "Evidence for a megareplicon covering megabases of centromeric chromosome Segments," Chromosome Res. 4(3):240-7 (1996) |
| | FU | Hosokawa et al., "Pituitary Carcinoma of Pars Distalis as a Common Neoplasm in Fischer-344 Rats," Toxicol. Pathol. 21: 283-287 (1993) |
| | FV | Hughes, R.G. and N. Turner, "Financial Aspects of Clinical Trials", Chapter 42 in <i>Principles and Practice of Pharmaceutical Medicine</i> , A.J. Fletcher, et al.(eds.), pp. 501-512, John Wiley & Sons, Ltd. (2002) |
| | FW | Humlova, Z. et al., "Vaccinia virus induces apoptosis of infected macrophages," J. General Virol., 83: 2821-2832 (2002) |
| | FX | Jain, R.K. and B.T. Fenton, "Intratumoral Lymphatic Vessels: A Case of Mistaken Identity or Malfunction?," Journal of the National Cancer Institute, 94(6): 417-421 (2002) |
| | FY | Jain, R.K., "Molecular regulation of vessel maturation," Nat. Med., 9(6): 685-693 (2003) |
| | FZ | Jemal, A. et al., "Cancer Statistics, 2003", CA Cancer J Clin, 53(1): 5-26 (2003) |
| | GA | Jeong, K.J. and S.Y. Lee, "Secretory Production of Human Leptin in <i>Escherichia coli</i> ," Biotechnol.Bioeng. 67:398-407 (2000) |
| | GB | Kaniga et al., "Homologs of the <i>Shigella</i> IpaB and IpaC Invasins are Required for <i>Salmonella typhimurium</i> Entry into Cultured Epithelial Cells," J. Bacteriol. 177: 3965-3971 (1995) |
| | GC | Kawa, A. and S. Arakawa, "The Effect of Attenuated Vaccinia Virus AS Strain on Multiple Myeloma; A Case Report," Japan. J. Exp. Med. 58(1): 79-81 (1987) |
| | GD | Keith, K.A. et al., "Evaluation of Nucleoside Phosphonates and Their Analogs and Prodrugs for Inhibition of Orthopoxvirus Replication," Antimicrob. Agents Chemothera., 47(7): 2193-2198 (2003) |
| | GE | Keresó, J. et al., "De novo chromosome formations by large-scale amplification of the centromeric region of mouse chromosomes," Chromosome Res. 4(3):226-39 (1996) |
| | GF | Kern, E.R., "In vitro activity of potential anti-poxvirus agents", Antiviral Research 57: 35-40 (2003) |

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| | GG | Kihara, A. and I. Pastan, "Analysis of Sequences Required for the Cytotoxic Action of a Chimeric Toxin Composed of Pseudomonas Exotoxin and Transforming Growth Factor α ," Bioconj.Chem. 5: 532-538 (1994) | | | | | |
| | GH | Kim, E.M. et al., "Overview analysis of adjuvant therapies for melanomaFa special reference to results from vaccinia melanoma oncolysate adjuvant therapy trials", Surgical Oncology, 10: 53-59 (2001) | | | | | |
| | GI | Kleer, C.G. et al., "Molecular biology of breast cancer metastasis Inflammatory breast cancer: clinical syndrome and molecular determinants," Breast Cancer Res. 2: 423-429 (2000) | | | | | |
| | GJ | Kneissl, M. et al., "Interaction and assembly of murine pre-replicative complex proteins in yeast and mouse cells," J Mol Biol. 327(1):111-28 (2003) | | | | | |
| | GK | Kolowsky K.S. et al., "Length of foreign DNA in chimeric plasmids determines the efficiency of its integration into the chromosome of the cyanobacterium Synechococcus R2," Gene 27(3):289-99 (1984) | | | | | |
| | GL | Kondo et al., "Activity of Immunotoxins Constructed with Modified Pseudomonas Exotoxin A Lacking the Cell Recognition Domain," J.Biol.Chem. 263: 9470-9475 (1988) | | | | | |
| | GM | Krauss, O. et al., "An investigation of incorporation of cellular antigens into vaccinia virus particles," Journal of General Virology, 83: 2347-2359 (2002) | | | | | |
| | GN | Kruse, M. et al., "Enzyme assembly after de novo synthesis in rabbit reticulocyte lysate involves molecular chaperones and immunophilins," J Biol Chem. 270(6):2588-94 (1995) | | | | | |
| | GO | Kubes, P., "Introduction: The complexities of leukocyte recruitment," Seminars in Immunol. 14: 65-72 (2002) | | | | | |
| | GP | Kunkel, E.J. and E.C. Butcher, "Plasma-cell homing," Nature Reviews Immunology, 3: 822-829 (2003) | | | | | |
| | GQ | Kwak, H. et al., "Poxviruses as vectors for cancer immunotherapy," Curr. Opin. Drug Disc. Develop., 6(2): 161-168 (2003) | | | | | |
| | GR | Langridge W.H. et al., "Detection of baculovirus gene expression in insect cells and larvae by low light video image analysis," J Virol Methods. 61(1-2):151-6 (1996) | | | | | |
| | GS | Langridge W.H. et al., "Uptake of DNA and RNA into cells mediated by electroporation," Methods Enzymol. 153:336-50. (1987) | | | | | |
| | GT | Langridge, W.H. and , A.A.Szalay, "Bacterial and coelenterate luciferases as reporter genes in plant cells," Chapter 37 in Methods Mol Biol. 82:385-96.(1998) | | | | | |
| | GU | Larson et al. "Triumph over mischance: a role for nuclear medicine in gene therapy," J Nucl Med. 38(8):1230-3 (1997) | | | | | |
| | GV | Lawrence J.C., "The bacteriology of burns", J. of Hospital Infection 6: 3-17 (1985) | | | | | |
| | GW | Lee et al., "The <i>lux</i> genes of the luminous bacterial symbiont <i>Photobacterium leiognathi</i> , of the ponyfish," Eur. J. Biochem. 201: 161-167 (1991) | | | | | |
| | GX | Legocki et al., "Bioluminescence in soybean root nodules: Demonstration of a general approach to assay gene expression <i>in vivo</i> by using bacterial luciferase," Proc. Natl. Acad. Sci 83: 9080-9084 (1986) | | | | | |
| | GY | Ley, K., "Integration of inflammatory signals by rolling neutrophils," Immunological Reviews, 186: 8-18 (2002) | | | | | |

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| | GZ | Ley, K., "The role of selectins in inflammation and disease", Trends in Molec. Med., 9(6): 263-268 (2003). | | | | | |
| | HA | Li et al "An engineered and assembled fusion protein of antitumor antibiotic lidamycin and scFV antibody directed against type IV collagenase" Yaouxue Xuebao 35(7) 488-91 (July, 2000) [English abstract on last page of article] | | | | | |
| | HB | Lindvall et al., "Grafts of Fetal Dopamine Neurons Survive and Improve Motor Function in Parkinson's Disease," Science 237:574-577 (1990) | | | | | |
| | HC | Liu, H et al., "Detection of GDNF secretion in glial cell culture and from transformed cell implants in the brains of live animals," Mol Genet Genomics. 266(4):614-23. (2001) | | | | | |
| | HD | Liu, J. et al., "Visualizing and quantifying protein secretion using a Renilla luciferase-GFP fusion protein," Luminescence. 15(1):45-49 (2000) | | | | | |
| | HE | Lorenz et al., "Isolation and expression of a cDNA encoding <i>Renilla reniformis</i> luciferase," PNAS USA 88: 4438-4442 (1991) | | | | | |
| | HF | Lorenz et al., "Expression of the Renilla reniformis luciferase gene in mammalian cells," J Biolumin Chemilumin. 11(1):31-7 (1996) | | | | | |
| | HG | Louie, A.Y. et al., "In vivo visualization of gene expression using magnetic resonance imaging," Nature Biotechnology, 18: 321-325 (2000) | | | | | |
| | HH | Luscinskas, F.W. et al., "Leukocyte transendothelial migration: A junctional affair," Seminars in Immunology, 14: 105-113 (2002) | | | | | |
| | HI | Luscinskas, F.W. et al., "The role of endothelial cell lateral junctions during leukocyte trafficking," Immunological Reviews, 186: 57-67 (2002) | | | | | |
| | HJ | Lusso, P., "Chemokines and Viruses: The Dearest Enemies," Virology, 273: 228-240 (2000) | | | | | |
| | HK | Lyford, J., "Gene therapy 'cause T-cell leukemia': Insertional mutagenesis pinpointed as cause of T-cell Leukemia in X-SCID gene therapy trial," The Scientist, (Daily News, October 20, 2003) pgs. 1-4 (2003) | | | | | |
| | HL | MacDonald, I.C. et al., "Cancer spread and micrometastasis development: quantitative approaches for in vivo models," BioEssays, 24: 885-893 (2002) | | | | | |
| | HM | MacLaren et al. "Receptive non-invasive imaging of the dopamine D2 receptor gene in living animals" Gene Therapy 6: 785-791 (1995) | | | | | |
| | HN | MacLeod R.A. et al., "Expression of genes from the marine bacterium <i>Alteromonas haloplanktis</i> 214 in <i>Escherichia coli</i> K-12," Arch Microbiol. 142(3):248-52 (1985) | | | | | |
| | HO | Maeda, H. et al., "Tumor vascular permeability and the EPR effect in macromolecular therapeutics: a review", J. Controlled Release, 65: 271-284 (2000) | | | | | |
| | HP | Mahy, B.W.J., "An overview on the use of a viral pathogen as a bioterrorism agent: why smallpox?", Antivir. Res., 57: 1-5 (2003) | | | | | |
| | HQ | Maina C.V. et al., "Molecular weight determination program," Nucleic Acids Res. 12(1 Pt 2):695-702 (1984) | | | | | |
| | HR | Makower, D. et al., "Phase II Clinical Trial of Intravesicular Administration of the Oncolytic Adenovirus ONYX-015 in Patients with Hepatobiliary Tumors with Correlative p53 Studies," Clin. Cancer Res., 9: 693-702 (2003) | | | | | |
| | HS | Mastrangelo, M.J. et al., "Poxvirus vectors: orphaned and underappreciated," J. Clin. Invest., 105(8): 1031-1034 (2000) | | | | | |

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| | | Filing Date December 3, 2004 | Group Art Unit 1645 |

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| | HT | Matz et al., "Fluorescent proteins from nonbioluminescent Anthozoa species," Nat.Biotech. 17: 969-973 (1999) |
| | HU | Mayerhofer, R et al., "Monitoring of spatial expression of firefly luciferase in transformed zebrafish," J Biolumin Chemilumin. 10(5):271-5 (1995) |
| | HV | McCart, J.A. et al., "Complex interactions between the replicating oncolytic effect and the enzyme/prodrug effect of vaccinia-mediated tumor regression," Gene Therapy, 7: 1217-1223 (2000) |
| | HW | McCart, J.A. et al., "Systemic Cancer Therapy with a Tumor-selective Vaccinia Virus Mutant Lacking Thymidine Kinase and Vaccinia Growth Factor Genes," Cancer Research, 61: 8751-8757 (2001) |
| | HX | McDonald, D.M. and P.L. Choyke, "Imaging of angiogenesis: from microscope to clinic," Nature Medicine, 9(6): 713-725 (2003) |
| | HY | Meager, A. et al., "The Development of the Regulatory Process in Europe for Biological Medicines: How it Affects Gene Therapy Products", Chapter 16 in <i>Gene Therapy Technologies, Applications and Regulations</i> , A. Meager (Ed.), John Wiley & Sons Ltd., pp. 319-346 (1999) |
| | HZ | Meighen, E.A. and R.B. Szittner, "Multiple Repetitive Elements and Organization of the <i>lux</i> Operons of Luminescent Terrestrial Bacteria," J. Bacteriol. 174(16):5371-5381 (1992) |
| | IA | Mengaud et al., "Expression in <i>Escherichia coli</i> and Sequence Analysis of the Listeriolysin O Determinant of <i>Listeria monocytogenes</i> ," Infect.Immun. 56(4): 766-772 (1988) |
| | IB | Middleton, J. et al., "Leukocyte extravasation: chemokine transport and presentation by the endothelium", Blood, 100(12): 3853-3860 (2002) |
| | IC | Moore et al. , "Measuring transferrin receptor gene expression by NMR imaging," Biochimica et Biophysica Acta 1402(3):239-249 (1998) |
| | ID | Moore, A.E., "Effects of Viruses on Tumors", Annu. Rev. Microbiol., 8: 393-402 (1954) |
| | IE | Moretta, A., "Natural Killer Cells and Dendritic Cells: Rendezvous in Abused Tissues", Nat. Rev. Immunol., 2: 957-964 (2002) |
| | IF | Morris, D.W. et al., "Plasmid vectors capable of transferring large DNA fragments to yeast," DNA. 1(1):27-36 (1981) |
| | IG | Moss, B., "Poxviridae: the viruses and their replication," Chapter 84 in Field's Virology, 4 th Edn., vol. 2, pp. 2849-2883. Edited by D. M. Knipe and P. M. Howley, Philadelphia: Lippincott Williams & Wilkins, (2001) |
| | IH | Moss, B., "Poxviridae: the viruses and their replication," Chapter 83 in Fields Virology, 3rd Edn, pp. 2637-2671. Edited by B. N. Fields, D. M. Knipe & P. M. Howley. Philadelphia: Lippincott-Raven (1996) |
| | II | Mountz et al. "Technetium-99m NeoTect imaging <i>in vivo</i> of T cells from hCAR transgenic mice," FASEB J. 16(5):A1211 March Meeting abstract (2002) |
| | IJ | Nagahari et al. "Secretion into the culture medium of a foreign gene product from <i>Escherichia coli</i> : use of the <i>ompF</i> gene for secretion of human β -endorphin." EMBO J. 4(13A):3589-92 (1985) |
| | IK | Nettleton, P.F. et al., "Parapoxviruses are strongly inhibited <i>in vitro</i> by cidofovir," Antivir. Res., 48: 205-208 (2000) |
| | IL | Newton et al. "Expression and characterization of recombinant human eosinophil-derived neurotoxin and eosinophil-derived neurotoxin-anti-transferrin receptor sFv," J. Biol. Chem.269(43):26739-45, (1994) |

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| | IM | Neyts et al., "Therapy and short-term prophylaxis of poxvirus infections: historical background and perspectives," <i>Antivir. Res.</i> 57: 25-33 (2003) |
| | IN | Nibbering et al. "Radiolabelled antimicrobial peptides for imaging of infections: a review," <i>Nucl Med Commun.</i> 19(12):1117-21 (1998) |
| | IO | Nichterlein et al., "Clinafloxacin (CI 960) is Superior to Standard Therapeutics in the Treatment of Murine Listeriosis and Salmonellosis," <i>Zentralbl.Bakteriol.</i> 286: 401-412 (1997) |
| | IP | Nisato, R.E. et al., "Lymphangiogenesis and tumor metastasis", <i>Thromb. Haemost.</i> , 90: 591-597 (2003) |
| | IQ | Nolan G.P., et al., "Plasmid mapping computer program," <i>Nucleic Acids Res.</i> 12(1 Pt 2):717-29 (1984) |
| | IR | Noti J.D. et al., "Organization and characterization of genes essential for symbiotic nitrogen fixation from <i>Bradyrhizobium japonicum</i> I110," <i>J Bacteriol.</i> 167(3):774-83 (1986) |
| | IS | Noti J.D. et al., "Site-directed Tn5 and transplacement mutagenesis: methods to identify symbiotic nitrogen fixation genes in slow-growing <i>Rhizobium</i> ," <i>Methods Enzymol.</i> 154:197-217 (1987) |
| | IT | Ober, B.T. et al., "Immunogenicity and Safety of Defective Vaccinia Virus Lister: Comparison with Modified Vaccinia Virus Ankara", <i>J. Virol.</i> , 76(15): 7713-7723 (2002) |
| | IU | O'Kane et al., "Visualization of Bioluminescence as a Marker of Gene Expression in <i>Rhizobium</i> -Infected Soybean Root Nodules," <i>J. Plant Mol. Biol.</i> 10: 387-399 (1988). |
| | IV | Olsson et al., "Engineering of monomeric bacterial luciferases by fusion of luxA and luxB genes in <i>Vibrio harveyi</i> ," <i>Gene</i> 81(2):335-47 (1989) |
| | IW | Olsson, O. et al., "The use of the luxA gene of the bacterial luciferase operon as a reporter gene," <i>Mol Gen Genet.</i> 215(1):1-9 (1988) |
| | IX | Overholser et al., "Experimental Bacterial Endocarditis after Dental Extractions in Rats with Periodontitis," <i>J. Infect. Dis.</i> 155(1): 107-112 (1987) |
| | IY | Padera, T.P. et al., "Lymphatic Metastasis in the Absence of Functional Intratumor Lymphatics", <i>Science</i> 296: 1883-1886 (2002) |
| | IZ | Paniacchi, D. et al., "Vaccinia virus vectors utilizing the β -galactosidase assay for rapid selection of recombinant viruses and measurement of gene expression," <i>Gene</i> , 47: 193-199 (1986) |
| | JA | Pardal, R. et al., "Applying the principles of stem-cell biology to cancer," <i>Nature Reviews Cancer</i> , 3: 895-902 (2003) |
| | JB | Parish, C.R., "Cancer immunotherapy: The past, the present and the future," <i>Immunology and Cell Biology</i> , 81: 106-113 (2003) |
| | JC | Pawelek, J.M. et al., "Bacteria as tumour-targeting vectors," <i>The Lancet Oncology</i> , 4: 548-556 (2003) |
| | JD | Pecora, A.L. et al., "Phase I Trial of Intravenous Administration of PV701, an Oncolytic Virus, in Patients With Advanced Solid Cancers," <i>Journal of Clinical Oncology</i> , 20(9): 2251-2266 (2002) |
| | JE | Peplinski, G.R. et al., "Vaccinia Virus For Human Gene Therapy," <i>Surgical Oncology Clinics of North America</i> , 7(3): 575-588 (1998) |
| | JF | Pluen, A. et al., "Role of tumor-host interactions in interstitial diffusion of macromolecules: Cranial vs. subcutaneous tumors," <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 98(8): 4628-4633 (2001) |
| | JG | Polverini et al., "Assay and Purification of Naturally Occuring Inhibitor of Angiogenesis," <i>Methods in Enzymology</i> 198:440-450 (1991) |

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| | JH | Pongor S. et al., "Microcomputer programs for prediction and comparative evaluation of protein secondary structure from nucleotide sequence data: application to ribulose-1,5-bisphosphate carboxylase sequences," DNA. 4(4):319-26 (1985) | | | | | |
| | JI | Pongor S. and A.A. Szalay, "Prediction of homology and divergence in the secondary structure of Polypeptides," Proc Natl Acad Sci U S A. 82(2):366-70 (1985) | | | | | |
| | JJ | Prasher et al., "Sequence Comparison of Complementary DNAs Encoding Aequorin Isotypes," Biochemistry 26: 1326-1332 (1987) | | | | | |
| | JK | Prasher et al., "Primary structure of the Aequorea victoris green-fluorescent protein," Gene 111: 229-233 (1992) | | | | | |
| | JL | Proudfoot, A.E.I. et al., "Strategies for Chemokine Antagonists as Therapeutics," Seminars in Immunology, 15: 57-65 (2003) | | | | | |
| | JM | Puhlmann et al. "Thymidine kinase-deleted vaccinia virus expressing purine nucleoside phosphorylase as a vector for tumor-directed gene therapy," Hum Gene Ther. 10(4):649-57 (1999) | | | | | |
| | JN | Quenelle, D.C. et al., "Efficacy of Multiple- or Single-Dose Cidofovir against Vaccinia and Cowpox Virus Infections in Mice," Antimicrobial Agents and Chemotherapy, 47(10): 3275-3280 (2003) | | | | | |
| | JO | Ramirez, J.C. et al., "Tissue distribution of the Ankara strain of vaccinia virus (MVA) after mucosal or systemic administration," Arch. Virol., 148: 827-839 (2003) | | | | | |
| | JP | Rangarajan, A. and R.A. Weinberg, "Comparative biology of mouse versus human cells: modeling human cancer in mice," Nature Reviews Cancer, 3: 952-959 (2003) | | | | | |
| | JQ | Ransohoff, R.M. et al., "Three or more routes for leukocyte migration into the central nervous system," Nat. Rev. Immunol., 3: 569-581 (2003) | | | | | |
| | JR | Reddy et al. "Folate-mediated targeting of therapeutic and imaging agents to cancers," Crit Rev Ther Drug Carrier Syst. 15(6):587-627 (1998) | | | | | |
| | JS | Reno, F., "Non-clinical Toxicology", Principles and Practice of Pharmaceutical Medicine, A.J. Fletcher et al.(eds.), ch.6: 55-64 (c2002) John Wiley & Sons Ltd. | | | | | |
| | JT | Ribas, A. et al., "Current Developments in Cancer Vaccines and Cellular Immunotherapy," Journal of Clinical Oncology, 21(12): 2415-2432 (2003) | | | | | |
| | JU | Ring, C.J.A., "Cytolytic viruses as potential anti-cancer agents," J. Gen. Virol., 83: 491-502 (2002) | | | | | |
| | JV | Rodriguez, J.F. et al., "Expression of the firefly luciferase gene in vaccinia virus: A highly sensitive gene marker to follow virus dissemination in tissues of infected animals," Proc. Natl. Acad. Sci. U.S.A., 85: 1667-1671 (1988) | | | | | |
| | JW | Rothenberg, M.L. et al., "Improving the evaluation of new cancer treatments: challenges and opportunities", Nat. Rev. Cancer, 3: 303-309 (2003) | | | | | |
| | JX | Ruef et al. "Sternal wound infection after heart operations in pediatric patients associated with nasal carriage of <i>Staphylococcus aureus</i> " J. of Thoracic and Cardiovascular Surgery 112(3): 681-686 (1996) | | | | | |
| | JY | Santoro, J. and M.E. Levison, "Rat Model of Experimental Endocarditis," Infect. Immun. 19(3): 915-918 (1978) | | | | | |
| | JZ | Schlör et al., "In vivo and in vitro studies on interactions between the components of the hemolysin (HlyA) secretion machinery of <i>Escherichia coli</i> ," Mol.Gen.Genet. 256: 306-319 (1997) | | | | | |
| | KA | Schmidt et al. "Generation of effective cancer vaccines genetically engineered to secrete cytokines using adenovirus-enhanced transferrin infection (AVET)," Gene. 190(1):211-6 (1997) | | | | | |

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| Other Documents (include Author, Title, Date, and Place of Publication) | | | | | | | |
| Examiner Initial | Desig. ID | Document | | | | | |
| | KB | Shapiro, D. and A.W. Fox, "Biotechnology Products and Their Development", Principles and Practice of Pharmaceutical Medicine, A.J. Fletcher, et al.(eds.), ch.17: 191-201, c2002 John Wiley & Sons | | | | | |
| | KC | Shariatmadari et al., "Improved technique for detection of enhanced green fluorescent protein in transgenic mice," Biotechniques 30:1282-1285 (2001) | | | | | |
| | KD | Shata, M.T. et al., "Optimization of recombinant vaccinia-based ELISPOT assay", J. Immunological Methods, 283: 281-289 (2003) | | | | | |
| | KE | Shenk, T., "Delivery systems for gene therapy: the adenovirus", Stem Cell Biology and Gene Therapy, Quesenberry, P.J. et al. (Eds.), ch.6: pp 161-178, c1998 Wiley-Liss, Inc. | | | | | |
| | KF | Shepherd, A.J., "Good Laboratory Practice in the Research and Development Laboratory", Gene Therapy Technologies, Applications and Regulations, A. Meager (Ed.), ch.19: 375-381 (c1999) John Wiley & Sons Ltd. | | | | | |
| | KG | Shimizu, Y. et al., "Immunotherapy of tumor-bearing mice utilizing virus help", Cancer Immunol. Immunother., 27: 223-227 (1988) | | | | | |
| | KH | Sinkovics, J. and J. Horvath, "New Developments in the Virus Therapy of Cancer: A Historical Review", Intervirology, 36: 193-214 (1993) | | | | | |
| | KI | Sinkovics, J.G. and J.C. Horvath, "Newcastle disease virus (NDV): brief history of its oncolytic strains", J. Clin. Virol., 16: 1-15 (2000) | | | | | |
| | KJ | Sinkovics, J.G. and J.C. Horvath, "Virus therapy of human cancers", Melanoma Research, 13: 431-432 (2003) | | | | | |
| | KK | Smee, D.F. and R.W. Sidwell, "A review of compounds exhibiting anti-orthopoxvirus activity in animal models", Antiviral Research, 57: 41-52 (2003) | | | | | |
| | KL | Smee, D.F. et al., "Effects of cidofovir on the pathogenesis of a lethal vaccinia virus respiratory infection in mice", Antivir. Res., 52: 55-62 (2001) | | | | | |
| | KM | Smith, G.L. and B. Moss, "Infectious poxvirus vectors have capacity for at least 25000 base pairs of foreign DNA", Gene, 25: 21-28 (1983) | | | | | |
| | KN | Smith, G.L. et al., "The formation and function of extracellular enveloped vaccinia virus", J. Gen. Virol., 83: 2915-2931 (2002) | | | | | |
| | KO | Somia, N. and I.M. Verma, "Gene Therapy: Trial and Tribulations", Nat. Rev. Genet., 1(2): 91-99 (2000) | | | | | |
| | KP | Spencer et al., "Unilateral Transplantation of Human Fetal Mesencephalic Tissue Into The Caudate Nucleus Of Patients with Parkinson's Disease", New England Journal of Medicine 327: 1541-1548 (1992) | | | | | |
| | KQ | Stehle, G. et al., "Plasma protein (albumin) catabolism by the tumor itself--implications for tumor metabolism and the genesis of cachexia", Critical Reviews in Oncology/Hematology, 26: 77-100 (1997) | | | | | |
| | KR | Stojdl, D.F. et al., "VSV strains with defects in their ability to shutdown innate immunity are potent systemic anti-cancer agents", Cancer Cell, 4:263-275 (2003) | | | | | |
| | KS | Sudimack et al. "Targeted drug delivery via the folate receptor." Adv Drug Deliv Rev. 41(2):147-62 (2000) | | | | | |
| | KT | Sutton et al. "In vivo adenovirus-mediated suicide gene therapy of orthotopic bladder cancer." Mol Ther. 2(3):211-7 (2000) | | | | | |

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| | KV | Suzuki, S. et al. "Coexpression of the partial androgen receptor enhances the efficacy of prostate-specific antigen promoter-driven suicide gene therapy for prostate cancer cells at low testosterone concentrations," Cancer Research 61(4):1276-1279 (2001) | | | | | |
| | KW | Symons, J.A. et al., "A study of the vaccinia virus interferon- γ receptor and its contribution to virus virulence", Journal of General Virology, 83: 1953-1964 (2002) | | | | | |
| | KX | Szalay A.A. et al., "Separation of the complementary strands of DNA fragments on polyacrylamide gels," Nucleic Acids Res. 4(5):1569-78 (1977) | | | | | |
| | KY | Szalay A.A. et al., "Genetic engineering of halotolerance in microorganisms: a summary," Basic Life Sci. 14:321-32 (1979) | | | | | |
| | KZ | Technology Evaluation Center, "Special Report: Vaccines for the Treatment of Malignant Melanoma", TEC Assessment Program, 16(4): 1-46 (2001) | | | | | |
| | LA | t'Hart, B.A. et al., "Gene therapy in nonhuman primate models of human autoimmune disease", Gene Therapy, 10: 890-901 (2003) | | | | | |
| | LB | Theuer et al., "A recombinant form of pseudomonas exotoxin directed at the epidermal growth factor receptor that is cytotoxic without requiring proteolytic processing," J.Biol.Chem. 267(24): 16872-16877 (1992) | | | | | |
| | LC | Timiryasova, T.M. et al., "Antitumor Effect of Vaccinia Virus in Glioma Model", Oncology Research, 11(3): 133-144 (1999) | | | | | |
| | LD | Timiryasova, T.M. et al., "Replication-deficient vaccinia virus gene therapy vector: evaluation of exogenous gene expression mediated by PUV-inactivated virus in glioma cells", Journal of Gene Medicine, 3: 468-477 (2001) | | | | | |
| | LE | Timiryasova, T.M. et al., "Vaccinia virus-mediated expression of wild-type p53 suppresses glioma cell growth and induces apoptosis." Int J Oncol. 14(5):845-54 (1999) | | | | | |
| | LF | Timiryasova, T.M. et al., "Visualization of Vaccinia Virus Infection Using the Renilla-Luciferase-GFP Fusion Protein", Bioluminescence & chemiluminescence: Proceedings of the 11th International Symposium on Bioluminescence Chemiluminescence: Asilomar Conference Grounds, Pacific Grove, Monterey, California: September 6-10 2000 / (eds.): Case, J.F. et al., World Scientific Publishing Co. (c2001), pages 457-460 | | | | | |
| | LG | Timpl, "Antibodies to Collagens and Procollagens," Methods Enzymol. 82: 472-498 (1982) | | | | | |
| | LH | Tjuvajev, J. et al., "Salmonella-based tumor-targeted cancer therapy: tumor amplified protein expression therapy (TAPET TM) for diagnostic imaging," J. Controlled Release, 74: 313-315 (2001) | | | | | |
| | LI | Toguchi et al., "Suicide Gene Therapy of C6 Glioma Cells Mediated by Replication-Deficient and Replication Competent Vaccinia Viruses," Cancer Gene Therapy 10: S32 (2003) presented at the Eleventh International Conference on Gene Therapy of Cancer, December 12-14, 2002, San Diego California | | | | | |
| | LJ | Tokugawa et al., "A model system for the continuous production of a heterologous protein using a novel secretion promoting factor which operates in Escherichia coli," J.Biotechnol. 37:33-37 (1994) | | | | | |
| | LK | Tokugawa et al., "A novel protein secretion factor from a Vibrio species which operates in Escherichia coli," J.Biotechnol. 35: 69-76 (1994) | | | | | |
| | LL | Tonetti DA et al "Stable transfection of an estrogen receptor beta cDNA isoform into MDA-MB-231 breast cancer cells," J Steroid Biochem Mol Biol. 87(1):47-55 (2003) | | | | | |
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| | LM | Tresco et al., "Polymer-encapsulated PC12 Cells: Long-Term Survival and Associated Reduction in Lesion-Induced Rotational Behavior", Cell Transplantation 1:255-264 (1992) | | |
| | LN | Tscharke, D.C. et al., "A model for vaccinia virus pathogenesis and immunity based on intradermal injection of mouse ear pinnae", J. Gen. Virol., 80: 2751-2755 (1999) | | |
| | LO | Tscharke, D.C. et al., "Dermal infection with vaccinia virus reveals roles for virus proteins not seen using other inoculation routes", Journal of General Virology, 83: 1977-1986 (2002) | | |
| | LP | Tseng, J.-C. et al., "In Vivo Antitumor Activity of Sindbis Viral Vectors", Journal of the National Cancer Institute, 94(23): 1790-1802 (2002) | | |
| | LQ | Tseng, J.-C. et al., "Systemic tumor targeting and killing by Sindbis viral vectors", Nat. Biotechnol., 22(1): 70-77 (2004) | | |
| | LR | Tsung, K. et al., "Immune Response Against Large Tumors Eradicated by Treatment with Cyclophosphamide and IL-12", J. Immunol., 160: 1369-1377 (1998) | | |
| | LS | Vanderplasschen, A. et al., "Antibodies against vaccinia virus do not neutralize extracellular enveloped virus but prevent virus release from infected cells and comet formation", Journal of General Virology, 78: 2041-2048 (1997) | | |
| | LT | Vanderplasschen, A. et al., "Intracellular and extracellular vaccinia virions enter cells by different mechanisms", Journal of General Virology, 79: 877-887 (1998) | | |
| | LU | Varghese, S. and S.D. Rabkin, "Oncolytic herpes simplex virus vectors for cancer virotherapy", Cancer Gene Therapy, 9: 967-978 (2002) | | |
| | LV | Vento, S. and F. Cainelli, "Infections in patients with cancer undergoing chemotherapy: aetiology, prevention, and treatment", Lancet, 4: 595-604 (2003) | | |
| | LW | Vestweber, D., "Regulation of endothelial cell contacts during leukocyte extravasation", Curr. Opin. Cell Biol., 14: 587-593 (2002) | | |
| | LX | Vile, R. et al., "The oncolytic virotherapy treatment platform for cancer: Unique biological and biosafety points to consider", Cancer Gene Therapy, 9: 1062-1067 (2002) | | |
| | LY | Vogel, J.R., "Outsourcing Clinical Drug Development Activities to Contract Research Organizations (CROs): Critical Success Factors", Principles and Practice of Pharmaceutical Medicine, A.J. Fletcher et al.(eds.), ch.40: 461-482 (c2002) John Wiley & Sons Ltd. | | |
| | LZ | Voisey et al. Elimination of internal restriction enzyme sites from a bacterial luminescence (luxCDABE) operon." Biotechniques 24(1):56, 58 (1998) | | |
| | MA | Wallack, M.K. et al., "A Phase III Randomized, Double-Blind, Multiinstitutional Trial of Vaccinia Melanoma Oncolysate-Active Specific Immunotherapy for Patients with Stage II Melanoma", Cancer, 75(1): 34-42 (1995) | | |
| | MB | Wallack, M.K. et al., "Increased Survival of Patients Treated With a Vaccinia Melanoma Oncolysate Vaccine", Annals of Surgery, 226(2): 198-206 (1997) | | |
| | MC | Wallack, M.K. et al., "Surgical Adjuvant Active Specific Immunotherapy for Patients with Stage III Melanoma: The Final Analysis of Data From a Phase III, Randomized, Double-Blind, Multicenter Vaccinia Melanoma Oncolysate Trial", J. Am. Coll. Surg., 187(1): 69-79 (1998) | | |
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| Substitute Form PTO-1449 (Modified) | | U.S. Department of Commerce Patent and Trademark Office | Attorney's Docket No. 17248-004US1/ 4804US | Application No. 10/516,785 |
|---|--------------|---|--|-------------------------------|
| List of Patents and Publications for Applicant's Information Disclosure Statement (37 CFR §1.98(b)) | | | Applicant Szalay et al. | |
| | | | Filing Date December 3, 2004 | Group Art Unit 1645 |
| Other Documents (include Author, Title, Date, and Place of Publication) | | | | |
| Examiner Initial | Desig. ID | Document | | |
| | ME | Wang Y. et al., "Renilla luciferase- Aequorea GFP (Ruc-GFP) fusion protein, a novel dual reporter for real-time imaging of gene expression in cell cultures and in live animals," Mol Genet Genomics. 268(2):160-8 (2002) | | |
| | MF | Wang, Y. et al., "The Renilla Luciferase-Modified GFP Fusion Protein is Functional in Transformed Cells", Bioluminescence & chemiluminescence: Proceedings of the 9th International Symposium on Bioluminescence Chemiluminescence: Woods Hole, Massachusetts, October 1996 / (eds.) Hastings, J.W. et al., John Wiley & Sons Ltd., pp. 419-422 (c1997) | | |
| | MG | Warrington et al. "Developing VDEPT for DT-diaphorase (NQO1) using an AAV vector plasmid," Int J Radiat Oncol Biol Phys. 42(4):909-12 (1998) | | |
| | MH | Wegner et al., "Cis-acting sequences from mouse rDNA promote plasmid DNA amplification and persistence in mouse cells: implication of HMG-I in their function", Nucleic Acids Research 17:9909-9932 (1989) | | |
| | MI | Weissleder et al. "Drug targeting in magnetic resonance imaging," Magnetic Resonance Quarterly. 8(1):55-63 (1992) | | |
| | MJ | Weissleder, T. et al., "In vivo magnetic resonance imaging of transgene expression", Nat. Med. , 6(3): 351-354 (2000) | | |
| | MK | Welling et al "Technetium-99m labelled antimicrobial peptides discriminate between bacterial infections and sterile inflammations." Eur J Nucl Med. 27(3):292-301 (2000) | | |
| | ML | Welling et al "Radiochemical and biological characteristics of 99mTc-UBI 29-41 for imaging of bacterial infections." Nucl Med Biol. 29(4):413-22 (2002) | | |
| | MM | West et al. "Identification of a somatodendritic targeting signal in the cytoplasmic domain of the transferrin receptor." J Neurosci. 17(16):6038-47 (1997) | | |
| | MN | Wharton, M. et al., "Recommendations for Using Smallpox Vaccine in a Pre-Event Vaccination Program", MMWR, 52(RR-7): 1-16 (2003) | | |
| | MO | Whitley, R.J., "Smallpox: a potential agent of bioterrorism", Antiviral Research 57: 7-12 (2003) | | |
| | MP | Williams J.G. and Szalay A.A., "Stable integration of foreign DNA into the chromosome of the cyanobacterium <i>Synechococcus</i> R2," Gene. 24(1):37-51 (1983). | | |
| | MQ | Winn et al., "Behavioral Recovery following Intrastratial Implantation of Microencapsulated PC12 Cells", Experimental Neurology 113:322-329 (1991) | | |
| | MR | Winn, S.R. et al., Polymer-encapsulated cells genetically modified to secrete human nerve growth factor promote the survival of axotomized septal cholinergic neurons," Proceedings of the National Academy of Science, 91:2324-2328 (1994). | | |
| | MS | Wisher, M., "Biosafety and product release testing issues relevant to replication-competent oncolytic viruses", Cancer Gene Therapy, 9: 1056-1061 (2002) | | |
| | MT | Wittrup, D., "Tumor Targeting Theory", IBC's 15 th Annual International Antibody Engineering Conference entitled Antibody Engineering: Forging the Future of Antibody Therapeutics, November 30 - December 3, 2003 - The Paradise Point Resort - San Diego, CA, pp. 1-17 | | |
| | MU | Wlodaver, C.G. et al., "Laboratory-acquired vaccinia infection", Journal of Clinical Virology, xxx: 1-5 (2003) | | |
| | MV | Wong, M.M. and E.N. Fish, "Chemokines: attractive mediators of the immune response", Semin. Immunol. 15: 5-14 (2003) | | |

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| | | | | Filing Date December 3, 2004 | | Group Art Unit 1645 | |
| Other Documents (include Author, Title, Date, and Place of Publication) | | | | | | | |
| Examiner Initial | Desig. ID | Document | | | | | |
| | MW | Yadav, R. et al., "Migration of leukocytes through the vessel wall and beyond," Thromb. Haemost., 90: 598-606 (2003) | | | | | |
| | MX | Yansura, D.G. and Henner D.J., "Use of the Escherichia coli lac repressor and operator to control gene expression in Bacillus subtilis," Proc. Natl. Acad. Sci USA 81: 439-443 (1984) | | | | | |
| | MY | Yu Y.A., "Visualization of molecular and cellular events with green fluorescent proteins in developing embryos: a review," Luminescence. 18(1):1-18 (2003) Erratum in: Luminescence. 2003 Jul-Aug;18(4):243 | | | | | |
| | MZ | Yu Y.A. et al., "A Renilla luciferase-Aequorea GFP (<i>ruc-gfp</i>) fusion gene construct permits real-time detection of promoter activation by exogenously administered mifepristone in vivo," Mol Genet Genomics. 268(2):169-78 (2002) | | | | | |
| | NA | Yu Y.A. et al., "Optical imaging: bacteria, viruses, and mammalian cells encoding light-emitting proteins reveal the locations of primary tumors and metastases in animals," Anal Bioanal Chem. 377(6):964-72 (2003) | | | | | |
| | NB | Yu, Y.A. et al. "Visualization of tumors and metastases in live animals with bacteria and vaccinia virus encoding light-emitting proteins," Nat Biotech. 22(3): 313-320 (2004) | | | | | |
| | NC | Yun A.C. et al. "Nitrogenase promoter- <i>lacZ</i> fusion studies of essential nitrogen fixation genes in Bradyrhizobium japonicum 1110," J Bacteriol. 167(3):784-91 (1986) | | | | | |
| | ND | Zamir et al. "Stable chromosomal integration of the entire nitrogen fixation gene cluster from Klebsiella pneumoniae in yeast," Proc Natl Acad Sci U S A. 78(6):3496-500 (1981) | | | | | |
| | NE | Zaucha, G.M. et al., "The Pathology of Experimental Aerosolized Monkeypox Virus Infection in Cynomolgus Monkeys (<i>Macaca fascicularis</i>)", Lab. Invest., 81: 1581-1600 (2001) | | | | | |
| | NF | Zeh, H.J. and D.L. Bartlett, "Development of a replication-selective, oncolytic poxvirus for the treatment of human cancers", Cancer Gene Therapy, 9: 1001-1012 (2002) | | | | | |
| | NG | Zhang et al., "Urothelium-specific Expression of an Oncogene in Transgenic Mice Induced the Formation of Carcinoma <i>in Situ</i> and Invasive Transitional Cell Carcinoma," Cancer Res. 59: 3512-3517 (1999) | | | | | |
| | NH | Zhu et al., " <i>Smad3</i> Mutant Mice Develop Metastatic Colorectal Cancer," Cell 94: 703-714 (1998) | | | | | |
| | NI | Zinkernagel, R.M., "Uncertainties — discrepancies in immunology," Immunological Reviews 185: 103-125 (2002) | | | | | |
| | NJ | Zinn et al., "Simultaneous evaluation of dual gene transfer to adherent cells by gamma-ray imaging," Nuclear Medicine and Biology 28(2):135-144 (2001) | | | | | |
| | NK | Zinn et al. "Noninvasive monitoring of gene transfer using a reporter receptor imaged with a high-affinity peptide radiolabeled with ^{99m} Tc or ¹⁸⁸ Re," J Nucl Med. 41(5):887-895 (2000) | | | | | |

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